

CLAIMS

1. A method to determine an analyte concentration of an anticoagulated plasma by performing at least two different measurements on a mixture of a blood sample corresponding to said anticoagulated plasma and of liquid reagent, comprising the steps of
- d) mixing a volume of said blood sample with a five-fold, or more, volume of said liquid reagent,
 - e) performing said at least two measurements on said mixture, at least one of which correlates with the hematocrit of said blood sample and at least one of which correlates with said analyte concentration, and
 - f) computing the results from the measurements when the volumes in a) are precise and accurate or when the hematocrit of said blood sample in b) is known to determine said analyte concentration of said anticoagulated plasma.
2. The method according to claim 1, wherein,
- g) the volume of blood in said mixture is within the range of 50% to 150% of an intended volume of blood,
 - b) the volume of reagent in said mixture is within the range of 70% to 120% of an intended volume of reagent, and
 - c) computing the results to determine the analyte concentration when the hematocrit of the blood sample is known.
3. The method according to claim 1, wherein said an intended volume of blood in a) is in the range of 5 to 40 μL and said intended volume of reagent is in the range 100 to 1000 μL .
4. The method according to claim 1, wherein said volume of blood in a) is in the range of 5 to 20 μL and said volume of reagent in the range of 150 to 600 μL .
5. The method according to claim 1, wherein said measurements in b) are performed in a tubular container with a smallest cross section dimension of at least 4 mm.
6. The method according to claim 1, wherein said measurements in b) are performed in a tubular container with a smallest cross section dimension in the range of 5 mm to 15 mm.

7. The method according to claim 1, wherein said method is calibrated with anticoagulated plasma that has been subjected to an anticoagulation process by addition of an anticoagulant selected from the group consisting of sodium, potassium and lithium salts of citrate, isocitrate, EDTA, oxalate, heparin and hirudin.

5

8. The method according to claim 1, wherein said anticoagulated plasma is a fluid derived from blood, which is selected from the group consisting of blood derived fluids composed of serum, heparinized plasma, hirudinized plasma, oxalated plasma, citrated plasma, isocitrated plasma, EDTA-plasma and heat-treated plasma.

10

9. The method according to claim 1, wherein said determination of analyte concentration is calibrated with anticoagulated blood, with known analyte concentration in the anticoagulated plasma, that has been subjected to an anticoagulation process by addition of an anticoagulant selected from the group consisting of sodium, potassium and lithium salts of citrate, isocitrate, EDTA, oxalate, heparin and hirudin.

15

10. The method according to claim 1, wherein said analyte is selected from the group consisting of prothrombin time (PT), fibrinogen, fibrinogen degradation products, fibrin degradation products (D-dimer), activated partial prothrombin time (APTT), activated clotting time (ACT), C-reactive protein (CRP), cholesterol, and glucose.

20

11. The method according to claim 1, wherein said measurement that correlates with said hematocrit in b) is based on one or more measurements of light with wavelengths in the range of 800 nm to 1100 nm.

25

12. The method according to claim 1, wherein said two or more measurements in b) are performed at ambient temperature in the range of 18° C to 40°C.

13. The method according to claim 1, wherein said reagent in a) contains 0.1 g/L, or more, fibrinogen.

30

14. The method according to claim 1, wherein said analyte concentration is PT expressed in INR, wherein, prior to said determination of analyte concentration in anticoagulated plasma, the analyte concentration is re-expressed in PT%.

35

15. The method according to claim 1, wherein clotting time of said mixture in a) is one of the at least one measurement that correlates with said analyte concentration in b).

16. A measurement and determination device for performing measurements on blood, anticoagulated blood and/or anticoagulated plasma samples, comprising
- 5 a) a holder for receiving a container containing liquid reagent from a specific lot, which container receives on operation of the device one of said samples for admixture with said liquid reagent,
- b) an energy source,
- c) a data processor,
- 10 d) a read only memory comprising a computing data set for one or more of said blood, anticoagulated blood and/or anticoagulated plasma sample admixtures, each computing data set being adapted to said specific lot,
- e) measurement means for performing two or more measurements on each admixture,
- 15 f) a display that shows user instructions and computed results based on data from d) and e), and
- g) control means for user control of the device.

17. An equipment kit equipped with an identification mark comprising a measurement and determination device for performing measurements on blood, anticoagulated blood
- 20 and/or anticoagulated plasma samples, and one or several liquid reagent(s) in container(s) equipped each with an identification mark related to said identification mark of said equipment kit.
